

GlaxoSmithKline to pay \$3 billion for health fraud

ADAM BRANDOLPH | Monday, July 2, 2012, 2:32 p.m.

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Pharmaceutical giant GlaxoSmithKline PLC will pay a \$3 billion settlement — including \$13 million to Pennsylvania — in the largest health care fraud settlement in U.S. history, officials said on Monday.

The combined criminal-civil fine will be the largest penalty paid by a drug company, said U.S. Deputy Attorney General James M. Cole.

The London-based corporation with Pennsylvania ties agreed to be monitored by government officials for five years to attempt to ensure the company's compliance, Cole said.

“Let me be clear — we will not tolerate health care fraud,” he said.

The company promoted two popular antidepressants for unapproved uses and failed to disclose important safety information on a third drug.

The GlaxoSmithKline CEO, Sir Andrew Witty, expressed regret and said the company has learned “from the mistakes that were made.”

“Today brings to resolution difficult, long-standing matters for GSK,” Witty said in a statement. “Whilst these originate in a different era for the company, they cannot and will not be ignored.”

Pennsylvania's share of the settlement will go to the state Department of Public Welfare, state Attorney General Linda Kelly said. A welfare spokeswoman did not know how the department would use the money.

Violations such as those in the GlaxoSmithKline case have been widespread in the pharmaceutical industry and have produced a series of hefty fines.

Critics say the industry regards fines as a cost of doing business and continues to aggressively promote drugs to doctors for uses not officially approved. Some companies have persuaded doctors to praise drugs to colleagues.

Such promotions have turned numerous drugs from mediocre sellers into blockbusters with more than \$1 billion in annual sales.

“Pharmaceutical companies have stockholders who are just as aggressive as those of IBM or Coca-Cola or McDonald's, and I think sometimes it comes down to their bottom line,” said Scott R. Drab, associate professor of pharmacy and therapeutics at the University of Pittsburgh School of Pharmacy.

Rob Peirce, an attorney with the Downtown law firm Robert Peirce & Associates who has represented clients against pharmaceutical companies, said it's common for pharmaceutical representatives to tout the benefits of drugs beyond their federally approved uses.

"We hope (that) pursuing claims on behalf of clients against the pharmaceutical industry curtails future negligent conduct," Peirce said. "And I think a \$3 billion penalty has to send a message."

Prosecutors said GlaxoSmithKline illegally promoted Paxil for treating depression in children from April 1998 to August 2003, even though the Food and Drug Administration never approved it for people younger than 18.

The corporation promoted Wellbutrin from January 1999 to December 2003 for weight loss, treatment of sexual dysfunction, substance addictions and attention deficit hyperactivity disorder, although it was approved only for treating major depressive disorder.

Justice Department officials said GlaxoSmithKline for years failed to report to the FDA on safety data from certain post-marketing studies and from two studies on the cardiovascular safety of the diabetes drug Avandia. Since 2007, the FDA has added warnings to the Avandia label to alert doctors about the potential for increased risk of congestive heart failure and heart attack.

The drugmaker agreed to resolve civil liability for promoting Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses.

In the civil settlement, the government said GlaxoSmithKline promoted Advair, Lamictal and Zofran for unapproved uses. The company resolved accusations that it paid kickbacks to doctors to prescribe those drugs as well as Imitrex, Lotronex, Flovent and Valtrex.

Drab said he could not understand why the company would withhold safety data "other than the fact that their drug would be diminished in prescription drug sales."

GlaxoSmithKline said that it disagreed with some Justice Department assertions and that its settlement with the government does "not constitute an admission of any liability or wrongdoing in the selling and marketing of Lamictal, Zofran, Imitrex, Lotronex, Flovent, Valtrex, Avandia or Advair products. The government also made allegations about Paxil, Wellbutrin that the company did not admit."

The company said the civil settlement "contains many allegations that are either inaccurate or incomplete, that selectively tell only parts of the story, and that draw unwarranted conclusions from disputed facts."

The Associated Press contributed to this report. Adam Brandolph is a staff writer for Trib Total Media. He can be reached at 412-391-0927 or abrandolph@tribweb.com.